CONFIDENTIAL

K061899

page 1 of 3

# J. 510(k) Summary

## Contact:

Joseph M. Ascenzi, Ph.D., RAC
Sr. Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Dr.
Irvine, CA 92618

Phone: 949-453-6352
Fax: 949-789-3900

OCT 26 2006

## Device Name:

| | |
|---|---|
| Trade Name: | EvoTech™ System |
| Proprietary Name: | EvoTech™ Integrated Endoscope Disinfection System |
| Classification: | Endoscopes and accessories |

## Predicate Device:

The EvoTech™ System claims equivalence to the EvoTech™ System (K040883) found substantially equivalent on April 5, 2005. The predicate device is cleared to high-level disinfect endoscopes that have been manually cleaned using the high level disinfectant CIDEX OPA Concentrate Solution.

## Device Description:

The EvoTech™ System is a two-basin washer/disinfector utilizing an enzymatic detergent and a concentrated high-level disinfectant, CIDEX OPA Concentrate Solution. Both the detergent and high-level disinfectant are diluted in the system to in-use concentrations. The EvoTech System is capable of cleaning endoscopes that have not been manually cleaned prior to placing in the EvoTech System.

## Intended Use:

The EvoTech™ System is intended for use as a washer/disinfector for reprocessing flexible endoscopes that do not contact normally sterile areas of the body

## Performance Data:

The EvoTech™ System is a washer/disinfector for use with an enzymatic detergent and the high-level disinfectant CIDEX® OPA Concentrate Solution at 50° with an exposure time of 5 min to achieve cleaning and high-level disinfection of flexible endoscopes.

The EvoTech System was tested to determine its ability to clean endoscopes. Both simulated use and in-use studies were completed. In both instances, endoscopes were contaminated and then processed in the "wash only" cycle in the EvoTech System. Residual soil was quantified for both protein and total organic carbon (TOC). In all instances the residuals were below the predefined limit of 8.5ug/cm$^2$.

Additionally, because the wash cycle is intended to eliminate the need for manual cleaning, studies were completed comparing the residual soil after manual cleaning according to the procedures of the Society for Gastroenterology Nurses and Associates (SGNA) and cleaning in the EvoTech System. In non-inferior trial, the washing of endoscopes in the EvoTech System was determined to be non-inferior to washing of endoscopes following the SGNA procedure.

Endoscopes used in clinical procedures were processed through the "wash only" cycle of the EvoTech System and then extracted for residual organic material. Processing in the EvoTech System reduced the residual protein and TOC in all channels and surfaces to less than the predefined acceptance criteria, indicating that the EvoTech System can clean clinically used endoscopes.

High-level disinfection of cleaned endoscopes was achieved. Endoscopes were contaminated with *Mycobacterium terrae* imbedded in soil. Soil was inoculated in channels and on the surfaces of endoscopes so that each endoscopes contained ≥8.5ug/cm$^2$ protein with >$10^7$ cfu/mL *M. terrae*. Endoscopes were disinfected in the EvoTech System without manual or automated washing. After processing the contaminated endoscopes through the disinfect cycle only in the EvoTech System, there was a >$10^6$ reduction in *M. terrae*.

## Conclusion:

Data presented in this submission indicate that the EvoTech System is substantially equivalent to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2006

Dr. Joseph M. Ascenzi
Senior Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

Re: K061899
Trade/Device Name: EvoTech™ Integrated Endoscope Disinfection System
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: October 6, 2006
Received: October 10, 2006

Dear Dr. Ascenzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

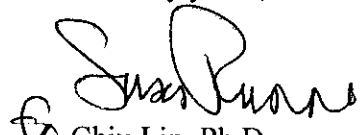
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Device Name:** EvoTech™ Integrated Endoscope Disinfection System K061899

**Indications for Use:**

The EvoTech™ System, a washer/disinfector, is indicated for use with high-level disinfectant CIDEX® OPA Concentrate and an enzymatic detergent (CIDEZYME GI) to achieve cleaning and high level disinfection of heat sensitive (>60°C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EvoTech System when selecting those cycles that contain a wash stage. (Manual cleaning is required when selecting the Disinfect Only or Disinfect/Alcohol Flush Cycles.)

Sheila K Murphy MD 10/26/06

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K061899

Prescription Use _____ AND/OR Over-the-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)